K033418

NOV 10 2003

510(k) Summary

This 510(k) summary of safety and effectiveness is submitted in accordance with the requirements set forth in 21 CFR 807.87(h).

Date:	October 17, 2003
Submitter:	Toshiba America Medical Systems, Inc. P.O. Box 2068, 2441 Michelle Drive, Tustin, CA 92781-2068
Submitter's Contact:	Paul Biggins Senior Manager, Regulatory Affairs Telephone: (714) 730-5000; Fax: (714) 730-1310
Device Proprietary Name:	TSX-101A/A and TSX-101A/C Aquilion Multislice CT Scanners
Common Name:	Scanner, Computed Tomography, X-Ray [Fed. Reg. No. 892.1750, Pro. Code: 90JAK]
Predicate Device(s):	TSX-101A/8 Aquilion 16 CT TSX-101A/7 Aquilion Super 4 CT

Description of this Device:
The Aquilion TSX101A/A and TSX-101A/C CT Scanner Systems are composed of a gantry, patient table, image acquisition hardware and software, an operator console and associated accessories. Materials and construction are similar to the Aquilion CT Scanner Multi-slice 16 (CGS-31A) [K022050] and the TSX-101A/7 Aquilion Super 4 CT Scanner [K031469], and are compliant with IEC60601-1 and associated collateral and particular standards, and applicable sections of 21 CFR Subchapter J.

Indications for Use:

The TSX-101A CT Scanners are indicated for head and whole body computed tomography applications.

Comparison with Predicate Devices
The TSX-101A/A and TSX-101A/C Computed Tomography Systems are modifications of, and are of comparable type and substantially equivalent to the currently marketed Toshiba TSX-101A/7 and TSXC-101A/8 CT Systems. They employ the same technological characteristics, are comparable in regards to primary concerns of safety and effectiveness, employ the same basic design, construction, materials and have the same intended use as the predicate devices.

Summary of Studies:
These devices have been evaluated for electrical, mechanical, and radiation safety. Furthermore they conform to applicable medical device safety and performance standards.

Conclusion
Intended use and technologies are the same as the predicate Toshiba devices listed above. The design and development process of the manufacturer conforms with 21 CFR 820 and ISO 9001/13485 quality systems. Additionally these devices conform to applicable medical device safety and performance standards. It is the opinion of Toshiba America Medical Systems that these devices are substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 10 2003

Toshiba America Medical Systems, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th NW
BUFFALO MN 55313

Re: K033418
Trade/Device Name: TSX-101A/A and TSX-101A/C
Aquilion CT Scanners
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography
x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: October 23, 2003
Received: October 27, 2003

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K033418

Device Name: TSX-101A/A and TSX-101A/C Aquilion CT Scanners

Indications for Use:

X-ray imaging of whole body - Computerized Tomography
Including:
Axial
Volumetric (Helical)
CT Fluoroscopy

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033418

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)